UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,598	02/14/2000	BERNARD CHARLES SHERMAN	2051-36	6120

23607 7590 08/06/2004

IVOR M. HUGHES, BARRISTER & SOLICITOR,
PATENT & TRADEMARK AGENTS
175 COMMERCE VALLEY DRIVE WEST
SUITE 200
THORNHILL, ON L3T 7P6
CANADA

EXAMINER	
VENKAT, JYOTHSNA A	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/485,598	SHERMAN, BERNARD CHARLES	
	Examiner	Art Unit	
	JYOTHSNA A VENKAT	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-15 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner of this application is changed from Amy Pulliam to **Jyothsna Venkat.**

Receipt is acknowledged of terminal disclaimer, response to office action, amendment and extension of time filed on 7/21/03. Claims 2,4, 16 are cancelled. Claims 1, 3, 5-15, and 17-20 are pending in the application and the status of the application is as follows:

The following new grounds of rejection are necessitated by the amendment dated 3/28/02, 11/27/02 and 7/21/03.

Specification

1. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

2. The attempt to incorporate subject matter into this application by reference to United States Pharmacopoeia at page 6, lines 10-16 is improper because the article which applicants are relying is essential material and the disintegration and dissolution claimed and disclosed in the specification appears to be critical element.

Claim Rejections - 35 USC § 112

3. Claims 1, 3, 5-15, and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is new matter rejection**.

The amendment dated **3/28/02** added the expression" having a disintegration time of at least 10-30 minutes---- 23rd edition". The support in the specification at page 6, line 11 is for " over 30 minutes". The specification at page 7, line 25 has support for " about 10 minutes". However the support for this expression is for specific ingredients and not for the broad claims claimed n the instant application.

The amendment dated **11/27/02** added the expression for dissolution, which is " of about 65% to about 80% in 20 minutes and about 80% to over 90% in 60 minutes. The support in the specification at page 6, lines 15-16 are for " about 65% in 25 minutes and 90% in 60 minutes". The specification at page 7, lines 30-31 have support for " over 80% in 20 minutes and over 90% in 60 minutes". However the support for this expression is for specific ingredients and not for the broad claims claimed in the instant application.

The amendment dated 7/21/03 added the expression" about 10 parts by weight of pure crystalline cefuroxime axetil and about 1 part by weight of the excipient ". There is no support for this expression in the specification.

In accordance with MPEP 714.02, applicants should specifically point out support for any amendments made to the disclosure.

4. Claims 1, 3, 5-15, and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is written description rejection.**

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to pure cefuroxime axetil and excipient with specific disintegration time and dissolution time " as determined by U. S. Pharmacoepia 23rd edition". The specification points out to specific page for disintegration time and dissolution time. The dissolution time and disintegration time appears to be critical for this specific crystalline compound, which appears to be at the point of novelty.

Claims employing the language " as determined by U. S. Pharmacoepia 23 rd edition", at the point of novelty, such as applicants', neither provide those elements required to practice the invention, nor "inform the public" during the life of the patent of the limits of the monopoly asserted.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3, 5-15, and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The expression" " as determined by U. S. Pharmacoepia 23 rd edition" lacks clarity and the metes and bound cannot be determined from the disclosure.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims1, 3, 5-6, 9-10, 1315, and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by U. S. Patent 5,063, 224 ('224).

Claim construction

The specification defines the meaning of co-precipitate at page 3, lines 6-9 as **"The co-precipitate is made by dissolving pure crystalline cefuroxime axetil and the water-soluble excipient in a solvent or combination of solvents and evaporating the solvent or solvents. high solubility so as to minimize the amount of solvent needed ".**

See example 2, line 49 for crystalline anhydrous R-cefuroxime axetil" Which reads on the claimed " pure crystalline cefuroxime axetil" . Note that the specification does not define the stereochemistry and it's the examiners position that the crystalline material claimed is in possession of the public. Example 2 also discloses evaporation of the solvent, which reads on the claimed " co-precipitate" defined by the specification. See also col.1, lines 44-49, col.2, lines 29-35 for the solvents ". Description of 12 solvents also anticipates the claimed ' acetone " . see col.2, lines 62-65 for evaporation of the solvent, see col.3, for cellulose derivatives, which reads

on disintegrants, see calcium stearate, which reads on the lubricant. See example 7 for sorbitol which reds on the claimed excipients and also the species. See col.3, line 59 for tablet. Since the compound meets all the requirement, the claimed dissolution time and disintegration time is inherent.

The affidavit submitted by Dr. Langer has overcome the 103 rejection over the patents to Duclos and James.

The patent 4,994, 567 is cited to show the state of the art. The patent discloses the claimed pure crystalline compound under preparation 2 and discloses excipients for amorphous form at c ol.6. However, the patent does not disclose or suggest the claimed co precipitate of pure crystalline cefuroxime axetil and a water-soluble excipients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A VENKAT whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Thursday, 9:30-7:30:1st and 2nd Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JYOTHSNA A VENKAT
Primary Examiner
Art Unit 1615

***

10.